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10/791,008

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EXAMINER

STIGELL, THEODORE J

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

07/06/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/791,008

Applicant(s)

CHAN ET AL.

Examiner

Theodore J. Stigell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

**DETAILED ACTION**

***Response to Amendment***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 8-12, 15-16, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Daneshvar (5,725,066). Daneshvar discloses a balloon catheter having a distal region and a proximal region comprising an elongate shaft (1) extending from the distal region to the proximal region and defining a working therebetween, the elongate shaft having an inner surface and an outer surface, an inflatable balloon (4) disposed about a portion of the distal region of the outer surface of the shaft such that the shaft extends through the balloon, and an external inflation lumen component (8,9) having an inner and an outer surface, and an inflation lumen in communication with the balloon, wherein the component is disposed longitudinally along the outer surface of elongate shaft such that the outer surface of the component is disposed adjacent the surface of the shaft, wherein the component has a distal end (7) disposed within the balloon, wherein the component can be considered a hypotube, wherein the distal region comprises an elastic, polymer tube, wherein the inflation lumen has a smaller diameter than a diameter of the shaft, wherein the component can be attached by shrinking, adhesive or thermal bonding (product-by-process limitations, not given

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patentable weight), wherein the balloon can be made of silicone, urethane, or poly-isoprene, wherein the proximal end of the component comprises a sealing valve (15), and wherein the balloon is attached to both the shaft and component.

Claims 1-4, 6, 8-16, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Shapiro (5,027,812). Shapiro discloses a balloon catheter having a distal region and a proximal region comprising an elongate shaft (11) extending from the distal region to the proximal region and defining a working therebetween, the elongate shaft having an inner surface and an outer surface, an inflatable balloon (12) disposed about a portion of the distal region of the outer surface of the shaft such that the shaft extends through the balloon, and an external inflation lumen component (13) having an inner and an outer surface, and an inflation lumen in communication with the balloon, wherein the component is disposed longitudinally along the outer surface of elongate shaft such that the outer surface of the component is disposed adjacent the surface of the shaft, wherein the component has a distal end (26) disposed within the balloon, wherein the component can be considered a hypotube, wherein the distal region comprises an elastic, polymer tube, wherein the inflation lumen has a smaller diameter than a diameter of the shaft, wherein the component can be attached by shrinking, adhesive or thermal bonding (product-by-process limitations, not given patentable weight), wherein the balloon can be made of silicone, urethane, or poly-isoprene, wherein the shaft comprises an internal metal braid or coil (11a), wherein the proximal end of the component comprises a sealing valve (30), and wherein the balloon is attached to both the shaft and component.

Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (6,217,547). Lee discloses a balloon catheter having a distal region and a proximal region comprising an elongate shaft (12) extending from the distal region to the proximal region and defining a working lumen (15) therebetween, the elongate shaft having an inner and an outer surface, an inflatable balloon (13) disposed about a portion of the distal region of the outer surface of the elongate shaft such that the shaft extends through the balloon, and an elongate inflation component (11) having an inflation lumen in fluid communication with the balloon, wherein the external inflation component is disposed longitudinally along the outer surface of the elongate shaft, wherein the inflation component is a sleeve disposed about the shaft, wherein the sleeve extends from the proximal region of the shaft to proximal of the distal end of the shaft, wherein the sleeve is spaced from the shaft, creating an annular inflation lumen (17) in fluid communication with the balloon, wherein the diameter of the working lumen tapers toward the distal end and the thickness of the sleeve remains constant along a length resulting in a catheter with a tapered distal region, wherein the distal end of the balloon is attached to the shaft and the proximal end is attached to the sleeve, and wherein the sleeve is a single layer polymer and is attached to an inflation hub (14) at the proximal end.

Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Wasicek et al. (6,117,106). Wasicek discloses a balloon catheter having a distal region and a proximal region comprising an elongate shaft (20) extending from the distal region to the proximal region and defining a working lumen (19) therebetween, the elongate

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shaft having an inner and an outer surface, an inflatable balloon (15) disposed about a portion of the distal region of the outer surface of the elongate shaft such that the shaft extends through the balloon, and an elongate inflation component (11) having an inflation lumen in fluid communication with the balloon, wherein the external inflation component is disposed longitudinally along the outer surface of the elongate shaft, wherein the inflation component is a sleeve disposed about the shaft, wherein the sleeve extends from the proximal region of the shaft to proximal of the distal end of the shaft, wherein the sleeve is spaced from the shaft, creating an annular inflation lumen (17) in fluid communication with the balloon, wherein the diameter of the working lumen tapers toward the distal end and the thickness of the sleeve remains constant along a length resulting in a catheter with a tapered distal region, wherein the distal end of the balloon is attached to the shaft and the proximal end is attached to the sleeve, and wherein the sleeve is a single layer polymer and is attached to an inflation hub (12,14) at the proximal end.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daneshvar (5,725,066) or Shapiro (5,027,812). Daneshvar or Shapiro discloses the claimed invention except for a polymer tube made of braided polymer tube or a hypotube made of nitinol. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use these materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (6,217,547) or Wasicek et al. (6,117,106). Lee or Wasicek disclose all of the limitations of the independent claim but fails to explicitly disclose an inflation lumen diameter of about 0.002 inches or 0.004 inches. Applicant has not disclosed that these specific limitations solve any stated problem or are for any particular purpose. The Applicant has not disclosed that these dimensions are needed to the exclusion of other or similar dimensions. Therefore, it appears that the catheters of Lee or Wasicek would perform equally well with the dimensions as stated by the Applicant. Accordingly, the use of these dimensions is deemed to be an obvious design consideration, which fails to patentably distinguish over the prior art of Lee or Wasicek.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-21 and 24 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Theodore J. Stigell

  
NICHOLAS D. LUCCHESI  
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